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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/522,699 03/10/00 CROWL R 4-31336P1 **EXAMINER** HM12/0927 THOMAS HOXIE NOLAN, P NOVATIS CORPORATION ART UNIT PAPER NUMBER PATENT AND TRADEMARK DEPT 564 MORRIS AVENUE 1644 SUMMIT NJ 07901-1027 DATE MAILED: 09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. **09/522,699**

Applicant(s)

Crowl et al.

Examiner

Patrick J. Nolan

Art Unit



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 2b) X This action is non-final. 2a) This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) X Claim(s) 1-21 _____ is/are pending in the application. 4a) Of the above, claim(s) _______ is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) _____ is/are objected to. 8) X Claims 1-21 are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. is/are objected to by the Examiner. 10) ☐ The drawing(s) filed on 11) The proposed drawing correction filed on ______ is: a) approved b) disapproved. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) ☐ All b) ☐ Some* c) ☐ None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). ___ 20) Other:

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Part III DETAILED ACTION

Claims 1-21 are pending.

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-4, 7-11 and 20-21, drawn to polynucleotides, host cells and vectors with said polynucleotides and methods of making a polypeptide by expressing said polynucleotides, classified in class 536, subclass 23.6 and 435 subclass 69.1.

Group II. Claims 5-6, drawn to a polypeptide, classified in class 530, subclass 350.

Group III. Claims 12-13, drawn to methods of diagnosing arthritis by detecting mRNA, classified in class 435, subclass 6.

Group IV. Claims 14-15, drawn to methods of diagnosing arthritis by detecting polypeptide with an antibody, classified in class 435, subclass 7.1.

Group V. Claims 16-19, drawn to antibodies, classified in 530 subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

3. Groups I, II and V are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

Groups III and IV are unique methods. They differ with respect to ingredients and method steps. A method of detecting mRNA and a method of detecting polypeptides with antibodies represent patentably distinct subject matter as evidenced by their divergent classification.

Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the antibody can be used to immunopurify the protein.

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Groups I, II, V and III are unrelated products and methods and are therefore patentably distinct.

- 4. Because a search of these five distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.
- 5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor or at least one claim remaining in the application. Any amendment of the inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (h).
- 7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.
- 9. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.

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Primary Examiner, Group 1640

September 26, 2001